

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Jeffery C. GARLAND et al.

Application No.: New US Application

Filed: April 2, 2004

Docket No.: 115622

For: METHOD AND APPARATUS FOR TRANSFERRING HEAT TO OR FROM AN ORGAN  
OR TISSUE CONTAINER

INFORMATION DISCLOSURE STATEMENT

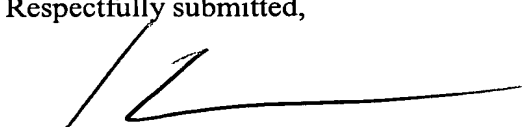
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR §1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

- ☒ 1. This Information Disclosure Statement is being filed (a) within three months of the U.S. filing date of this non-CPA application, OR (b) before the mailing date of a first Office Action on the merits in the present application. No certification or fee is required.
- ☒ 2. Relevance of the references Nos. 13, 43, 66-67, 72, 74, 79, 82-83, 108, 121, 124, 138-139, 141-146 and 159 is discussed in the present specification.
- ☒ 3. The present application was filed or entered the U.S. National Stage of the PCT after June 30, 2003. In accordance with the June 11, 2003, Notice waiving the requirements of 37 CFR §1.98(a)(2)(i), copies of any U.S. patents and patent application publications are not attached.

Respectfully submitted,

  
William P. Berridge  
Registration No. 30,024

Kevin M. McKinley  
Registration No. 43,794

WPB:KMM/tmw

Date: April 2, 2004

**OLIFF & BERRIDGE, PLC**  
**P.O. Box 19928**  
**Alexandria, Virginia 22320**  
**Telephone: (703) 836-6400**

<p>DEPOSIT ACCOUNT USE AUTHORIZATION Please grant any extension necessary for entry; Charge any fee due to our Deposit Account No. 15-0461</p>
--

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 115622		APPLICATION NO. New U.S. Patent Application	
INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)				APPLICANTS Jeffery C. GARLAND et al.			
				FILING DATE April 2, 2004			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
	1	5,699,793	12/23/1997	Brasile			
	2	5,843,024	12/01/1998	Brasile			
	3	5,702,881	12/30/1997	Brasile et al.			
	4	5,643,712	07/01/1997	Brasile			
	5	3,545,221	12/08/1970	Swenson et al.			
	6	1,682,344	08/28/1928	Lesieur			
	7	1,916,658	07/04/1933	Davidson			
	8	3,406,531	10/22/1968	Swenson et al.			
	9	3,607,646	10/21/1971	de Roissart			
	10	3,632,473	01/04/1972	Belzer			
	11	3,639,084	02/01/1972	Goldhaber			
	12	3,660,241	05/02/1972	Michielsen			
	13	3,738,914	06/12/1973	Thorne et al.			
	14	3,753,865	08/21/1973	Belzer et al.			
	15	3,772,153	11/13/1973	de Roissart			
	16	3,777,507	12/11/1973	Burton et al.			
	17	3,810,367	05/14/1974	Peterson			
	18	3,843,455	10/22/1974	M. Bier			
	19	5,681,740	10/28/1997	Messier et al.			
	20	3,881,990	05/06/1975	Burton et al.			
	21	3,892,628	07/01/1975	Thorne et al.			
	22	3,914,954	10/28/1975	Doerig			
	23	4,186,565	02/05/1980	Toledo-Pereyra			
	24	4,231,354	11/04/1880	Kurtz et al.			
	25	60/459,981	04/04/2003	David W. WRIGHT et al.			
	26	60/460,875	04/08/2003	David W. WRIGHT et al.			

Date: April 2, 2004

	27	3,962,439	06/08/1976	Yokoyama et al.		
	28	3,995,444	12/07/1976	Clark et al.		
	29	4,242,883	01/06/1981	Toledo-Pereyra		
	30	4,243,883	06/06/1981	Schwarzmann		
	31	4,378,797	04/05/1983	Osterholm		
	32	4,393,863	07/19/1983	Osterholm		
	33	4,445,500	05/01/1984	Osterholm		
	34	4,451,251	05/29/1984	Osterholm		
	35	4,462,215	07/31/1984	Kuraoka et al.		
	36	4,471,629	09/18/1984	Toledo-Pereyra		
	37	4,474,016	10/02/1984	Winchell		
	38	4,502,295	03/05/1985	Toledo-Pereyra		
	39	4,559,298	12/17/1985	Fahy		
	40	4,494,385	12/22/1985	Kuraoka et al.		
	41	4,596,250	06/24/1986	Beisang, III et al.		
	42	4,618,586	10/21/1986	Walker		
	43	4,629,686	12/16/1986	Gruenberg		
	44	4,657,532	04/14/1987	Osterholm		
	45	4,666,425	05/19/1987	Fleming		
	46	4,704,029	11/03/1987	Van Heuvelen		
	47	4,723,974	02/09/1988	Ammerman		
	48	4,745,759	05/24/1988	Bauer et al.		
	49	4,766,740	08/30/1988	Bradley et al.		
	50	4,801,299	01/31/1989	Brendel et al.		
	51	4,837,390	06/06/1989	Reneau		
	52	4,879,283	11/07/1989	Belzer et al.		
	53	4,951,482	08/28/1990	Gilbert		
	54	4,958,506	09/25/1990	Guilhem et al.		
	55	5,003,787	04/02/1991	Zlobinsky		
	56	5,028,588	07/02/1991	Hoffman et al.		
	57	5,036,097	07/30/1991	Floyd et al.		
	58	5,047,395	09/10/1991	Wu		
	59	5,051,352	09/24/1991	Martindale et al.		
	60	5,066,578	11/19/1991	Wikman-Coffelt		
	61	5,085,630	02/04/1992	Osterholm et al.		
	62	5,110,721	05/05/1992	Anaise et al.		

	63	5,130,230	07/14/1992	Segall et al.		
	64	5,141,847	08/25/1992	Sugimachi et al.		
	65	5,145,771	09/08/1992	Lemasters et al.		
	66	5,149,321	09/22/1992	Klatz et al.		
	67	5,157,930	10/27/1992	McGhee et al.		
	68	5,200,176	04/06/1993	Wong et al.		
	69	5,216,032	06/01/1993	Manning		
	70	5,217,860	06/08/1993	Fahy et al.		
	71	5,234,405	08/10/1993	Klatz et al.		
	72	5,285,657	02/15/1994	Bacchi et al.		
	73	5,328,821	07/12/1994	Fisher et al.		
	74	5,338,662	08/16/1994	Sadri		
	75	5,356,771	10/18/1994	O'Dell		
	76	5,362,622	11/08/1994	O'Dell et al.		
	77	5,383,854	01/24/1995	Safar et al.		
	78	5,385,821	01/31/1995	O'Dell et al.		
	79	5,395,314	03/07/1995	Klatz et al.		
	80	5,434,045	07/18/1995	Jost		
	81	5,437,633	08/01/1995	Manning		
	82	5,472,876	12/05/1995	Fahy		
	83	5,584,804	12/17/1996	Klatz et al.		
	84	5,586,438	12/24/1996	Fahy		
	85	5,599,659	02/04/1997	Brasile et al.		
	86	5,712,084	01/27/1998	Osgood		
	87	3,881,990	05/06/1975	BURTON et al.		
	88	3,712,583	01/23/1973	MARTINDALE et al.		
	89	5,051,352	09/24/1991	MARTINDALE et al.		
	90	3,845,974	11/05/1974	PELLOUX-GERVAIS		
	91	5,013,303	05/01/1991	TAMARI et al.		
	92	5,879,329	03/09/1999	GINSBURG		
	93	5,928,182	07/07/1999	KRAUS et al.		
	94	5,326,706	07/05/1994	Yland et al.		
	95	6,024,698	02/15/2000	Brasile		
	96	6,100,082	08/08/2000	Hassanein		
	97	6,046,046	04/04/2000	Hassanein		
	98	5,965,433	10/12/1999	Gardetto et al.		

	99	5,823,986	10/20/1998	Peterson		
	100	5,730,720	03/24/1998	Sites et al.		
	101	5,716,378	02/10/1998	Minten		
	102	5,622,429	04/22/1997	Heinze		
	103	4,462,215	0731//1984	Kuraoka et al.		
	104	4,494,385	01/22/1985	Kuraoka et al.		
	105	5,356,771	10/18/1994	O'Dell		
	106	5,362,622	11/08/1994	O'Dell et al.		
	107	5,385,821	01/31/1995	O'Dell et al.		
	108	5,217,860	06/08/1993	Fahy et al.		
	109	5,472,876	12/05/1995	Fahy		
	110	5,586,438	12/24/1996	Fahy		
	111	5,723,282	03/03/1998	Fahy et al.		
	112	5,821,045	10/13/1998	Fahy et al.		
	113	5,856,081	01/05/1999	Fahy		
	114	4,951,482	08/28/1990	Gilbert		
	115	4,837,390	06/06/1989	Reneau		
	116	4,717,548	01/05/1988	Lee		
	117	4,473,637	09/25/1984	Guibert		
	118	4,471,629	09/18/1984	Toledo-Pereyra		
	119	4,242,883	01/06/1981	Toledo-Pereyra		
	120	4,186,565	02/05/1980	Toledo-Pereyra		
	121	3,995,444	12/07/1976	Clark et al.		
	122	3,935,065	01/27/1976	Doerig		
	123	3,914,954	10/28/1975	Doerig		
	124	3,892,628	07/01/1975	Thorne et al.		
	125	3,881,990	05/06/1975	Burton et al.		
	126	3,877,843	04/15/1975	Fischel		
	127	3,843,455	10/22/1974	Bier		
	128	3,810,367	05/14/1974	Peterson		
	129	3,777,507	12/11/1973	Burton et al.		
	130	3,753,865	08/21/1973	Belzer et al.		
	131	3,738,914	06/12/1973	Thorne et al.		
	132	3,660,241	05/02/1972	Michielsen		
	133	3,639,084	02/01/1972	Goldhaber		
	134	3,654,085	04/04/1972	Norr et al.		

	135	3,632,473	01/01/1972	Belzer et al.		
	136	3,545,221	12/08/1970	Swenson et al.		
	137	3,406,531	10/22/1968	Swenson et al.		
	138	5,494,822	02/27/1996	Sadri		
	139	5,476,763	12/19/1995	Bacchi et al.		
	140	6,677,150	01/13/2004	Alford et al.		
	141	6,673,594	01/06/2004	Owen et al.		
	142	5,709,654	01/20/1998	Klatz et al.		
	143	5,752,929	05/19/1998	Klatz et al.		
	144	5,827,222	10/27/1998	Klatz et al.		
	145	4,745,759	05/24/1988	Bauer et al.		
	146	5,051,352	09/24/1991	Martindale et al.		

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS
	147	WO 00/18226	04/06/2000	WIPO		
	148	WO 96/30111	10/03/1996	WIPO		
	149	WO 96/32074	10/17/1996	WIPO		
	150	WO 96/32157	10/17/1996	WIPO		
	151	WO 97/28449	08/07/1997	WIPO		
	152	WO 96/12191	04/25/1996	WIPO		
	153	WO 96/31779	10/10/1996	WIPO		
	154	WO 97/22003	06/19/1997	WIPO		
	155	WO 96/29865	10/03/1996	WIPO		
	156	WO 94/06292	03/31/1994	WIPO		
	157	WO 91/09520	07/11/1991	WIPO		
	158	WO 86/00812	12/13/1986	WIPO		
	159	WO 88/05261	07/28/1998	WIPO		

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

	160	"RANDOMIZED CLINICAL STUDY OF THIOPENTAL LOADING IN COMATOSE SURVIVORS OF CARDIAC ARREST", <u>The New England Journal of Medicine</u> , Vol. 314, No. 7, pgs. 397-403, Feb. 1996.
	161	"FREE RADICALS AND MYOCARDIAL ISCHEMIA AND REPERFUSION INJURY", Paul J. Simpson et al., <u>J Lab Clin Med.</u> , pgs. 13-30, July 1987.
	162	"DEVELOPMENT OF AN ISOLATED PERFUSED DOG KIDNEY WITH IMPROVED FUNCTION", William H. Waugh et al., <u>American Journal of Physiology</u> , Vol. 217, No. 1, July 1969.
	163	"VARIATIONS IN VASCULAR RESISTANCE OF ISOLATED RAT HEARTS DURING NORMOTHERMIC AND HYPOTHERMIC EXPERIMENTS", C.G. Adem et al., <u>J. Biomed. Engng.</u> , Vol. 3(2), pgs. 128-133, 1981.

	164	"EFFECT OF PHARMACOLOGIC AGENTS ON THE FUNCTION OF THE HYPOTHERMICALLY PRESERVED DOG KIDNEY DURING NORMOTHERMIC REPERFUSION", Rutger J. Ploeg et al., <u>Surgery</u> , Vol. 103, No. 6, pgs. 676-682, June 1988.
	165	"THE BENEFICIAL EFFECT OF INTERMEDIATE NORMOTHERMIC PERFUSION DURING COLD STORAGE OF ISCHEMICALLY INJURED KIDNEYS", Jos G. Maessen et al., <u>Transplantation</u> , Vol. 47, No. 3, pgs. 409-414, March 1989.
	166	"THE ASYSTOLIC, OR NON-HEARTBEATING, DONOR", Gauke Kootstra, <u>Transplantation</u> , Vol. 63, No. 7, pgs. 917-921, 1997.
	167	"NORMOTHERMIC RENAL ARTERY PERFUSION: A COMPARISON OF PERFUSATES", John D. Hughes et al., <u>Annals of Vascular Surgery</u> , Vol. 10, pgs. 123-130, 1996.
	168	"IS NORMOTHERMIC PRESERVATION AN ALTERNATIVE TO HYPOTHERMIC PRESERVATION?", R. N. Dunn et al., <u>Organ Preservation Basic and Applied Aspects</u> , Chapter 38, pgs. 273-277, 1982.
	169	"STUDIES OF CONTROLLED REPERFUSION AFTER ISCHEMIA", Pierre L. Julia, MD et al., <u>The Journal of Thoracic and Cardiovascular Surgery</u> , Vol. 101, No. 2, pgs. 303-13, Feb. 1991.
	170	"URINARY $\pi$ -CLASS GLUTATHIONE TRANSFERASE AS AN INDICATOR OF TUBULAR DAMAGE IN THE HUMAN KIDNEY", Dr. Anders Sundberg et al., <u>Nephron</u> , Vol. 67, pgs. 308-316, 1994.
	171	"EFFECT OF ISCHEMIA AND 24 HOUR REPERFUSION ON ATP SYNTHESIS IN THE RAT KIDNEY", C.E. Irazu et al., <u>Journal of Experimental Pathology</u> , Vol. 4, No. 1, pgs. 29-36, 1989.
	172	"INTERMEDIATE NORMOTHERMIC HEMOPERFUSION OF RAT KIDNEYS: FUNCTIONAL ASPECTS AND A STUDY INTO THE EFFECT OF FREE RADICAL SCAVENGERS", A.O. Gaber, <u>Transplantation Proceedings</u> , Vol. XX, No. 5, pgs. 896-898, Oct. 1998.
	173	"IMPROVEMENT OF POSTISCHEMIC KIDNEY FUNCTION BY REPERFUSION WITH A SPECIFICALLY DEVELOPED SOLUTION (BT01)", Pierre Julia, MD et al., <u>Annals of Vascular Surgery</u> , Vol. 9, pgs. S-81-s-88, 1995.
	174	"ISCHEMIA WITH INTERMITTENT REPERFUSION REDUCES FUNCTIONAL AND MORPHOLOGIC DAMAGE FOLLOWING RENAL ISCHEMIA IN THE RAT", Richard S. Frank, MD et al., <u>Annals of Vascular Surgery</u> , Vol. 7, No. 2, pgs. 150-155, 1993.
	175	"GRAFT CONDITIONING OF LIVER IN NON-HEART-BEATING DONORS BY AN ARTIFICIAL HEART AND LUNG MACHINE IN SITU", T. Endoh et al., <u>Transplantation Proceedings</u> , Vol. 28, No. 1, pgs. 110-115, Feb. 1996.
	176	"MACHINE PERFUSION OF ISOLATED KIDNEY AT 37°C USING PYRIDOXALATED HEMOGLOBIN-POLYOXYETHYLENE (PHP) SOLUTION, UW SOLUTION AND ITS COMBINATION", T. Horiuchi et al., <u>Biomaterials, Art. Cells &amp; Immob. Biotech</u> , Vol. 20, Nos. 2-4,, pgs. 549-555, 1992.
	177	"ANALYSIS OF THE OPTIMAL PERFUSION PRESSURE AND FLOW RATE OF THE RENAL VASCULAR RESISTANCE AND OXYGEN CONSUMPTION IN THE HYPOTHERMIC PERFUSED KIDNEY", R. Grundmann, M.D. et al., <u>Surgery</u> , Vol. 77, No. 3, pp. 451-461, March 1975.
	178	"AN EXPERIMENTAL MODEL FOR ASSESSMENT OF RENAL RECOVERY FROM WARM ISCHEMIA", Paula Jablonski et al., <u>Transplantation</u> , Vol. 35, No. 3, pp. 198-204, March 1983.
	179	B.G. Rijkmans et al., "Six-Day Canine Kidney Preservation, Hypothermic Perfusion Combined with Isolated Blood Perfusion," February 1984, pp. 130-134.
	180	"INTERMEDIATE NORMOTHERMIC PERFUSION DURING COLD STORAGE OF ISCHEMICALLY INJURED KIDNEY," J.G. Maessen et al., <u>Transplantation Proceedings</u> , Vol. 21, No. 1, February 1989, pp. 1252-1253
EXAMINER		DATE CONSIDERED
Examiner:	Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Date: April 2, 2004